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| D:\nda\2016\memo\nda logo.jpg | **National Drug Authority**Plot No. 46 - 48 Lumumba Avenue, P.O. Box 23096, Kampala, Uganda. email: ndaug@nda.or.ug; website: [www.nda.or.ug](http://www.nda.or.ug) Tel: +256-414-255665, +256-414-347391/2 |  |
| 5. Format for Labelling EctoparasiticideTrial Products |

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*Outer/carton labels & Unit Pack*

**4.1** The following information shall be presented on the labeling of the product for trial:

|  |  |  |
| --- | --- | --- |
| *Parameters*  | *Outer/carton labels*  | *Unit Pack*  |
| Study No. or Protocol  | ?  | ?  |
| Group code  | ?  | ?  |
| Product name or code  | ?  | ?  |
| Dosage form  | ?\*\*  | ?\*\*  |
| Name of active substance  | ?\*\*  | ?\*\*  |
| Strength of active substance | ?\*\*  | ?\*\*  |
| Dilution for different species  | ?  | ?  |
| Batch number  | ?\*\*  | ?\*\*  |
| Manufacturing date or retest date  | ?  | ?  |
| Expiry date  | ?  | ?  |
| For Trial Use Only  | ?  | ?  |
| Name and address of manufacturer or final release or product owner (corporate address)or sponsor  | ?\*\*\*  | ?\*\*\*  |
| Route of administration  | ?  | ?  |
| Storage conditions  | ?  | ?  |
| Pack sizes (unit/Vol)  | ?  | ? |

\*\* Where applicable

\*\*\* With letter of authorization

If the product is supplied without an outer carton, the information that is required on the outer carton should be stated on the inner carton.